SunTech Medical®

K070750

SunTech Medical, Inc.
Abbreviated 510(k) Submission
247
510(k) Summary
March 16, 2007

MAY - 2 2007

(1) Submitter information

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Date prepared:	March 16, 2007

(2) Name of Device

Trade Name:	247
Common Name:	NIBP Monitor
Classification name:	Noninvasive blood pressure measurement system, 870.1130

(3) Legally-marketed predicate devices

Sun Tech Medical has identified Welch Allyn's Spot Vital Signs, K002530, as the predicate device for the 247.

The 247 is substantially equivilent to this device.

(4) Description

The 247 BP, Temperature and Pulse Oximeter device, a microprocessor based non-invasive blood pressure, predictive temperature and oxygen saturation measurement system, uses oscillometric signals to determine blood pressure, oral, rectal or auxiliary probes to determine temperature and an optical finger sensor for oxygen saturation. An internal electric pump is used to inflate the cuff. Deflation of the cuff is controlled by two valves. Implementation of Pulse Oximetry and temperature is achieved through the incorporation of OEM devices from companies with currently marketed products and accessories.

(5) Intended Use

The *SunTech Medical 247* NIBP , Temperature, and Pulse Oximeter device is indicated for use in measuring and displaying Systolic and Diastolic blood pressures, heart rate, temperature, and functional saturation of arterial hemoglobin (SpO_2) of adult and pediatric patients in hospitals, medical facilities, clinics, physicians offices, and other subacute environments.

(6) Comparison to Predicate Devices

The 247 has the same basic construction as the predicate device. Both devices are microprocessor controlled and the devices utilize similar circuitry. Both devices measure NIBP, SpO2, and body temperature. Neither device is intended to monitor the patient's vital signs. Both devices utilize the same measurement ranges for the various vital signs parameters being measured. Both devices are intended for adult and pediatric populations.

(7) Testing and Validations

The 247 has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- AAMI SP10: 2002
- IEC 60601-1:1996
- IEC 60601-1-2:2001
- IEC 60601-1-4:2000
- ISO 9919:1992
- E1112-00:2006
- Functional Specification, (SunTech document # 99-0049-XX-FS)

(8) Conclusion

The 247 is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2007

SunTech Medical, Inc.
c/o Mr. Chuck Setzer
Regulatory Manager
507 Airport Blvd., Suite 117
Morrisville, NC 27560-8200

Re: K070750
Trade Name: 247 BP Device
Regulation Number: 21 CFR 870.1130, 21 CFR 870.2700, and 21 CFR 880.2910
Regulation Name: Noninvasive Blood Pressure Measurement System; Oximeter; and, Clinical Electronic Thermometer
Regulatory Class: Class II (two)
Product Code: DXN, MUD, and FLL
Dated: March 16, 2007
Received: March 19, 2007

Dear Mr. Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K070750

Device Name: 247

Indications for Use:

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Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Burnsworth

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070750